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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,610	08/22/2003	Lola M. Reid	320727.00123	8277

27160 7590 01/11/2005

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EXAMINER	
WOITACH, JOSEPH T	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/645,610	REID ET AL.	
	Examiner	Art Unit	
	Joseph T. Woitach	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the c rrespondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *11-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This application filed August 22, 2003, is a continuation of 09/534,487, filed March 24, 2000, which is a continuation of 09/115,920, filed July 15, 1998, now US Patent 6,146,889, which a continuation of 08/751,546, filed November 18, 1996, now US Patent 5,789,246, which is a divisional of 08/265,696, filed June 24, 1994, now abandoned, which is a continuation of 07/741,128, filed August 7 1991, now abandoned.

Claims 1-20 are pending.

Election/Restrictions

Applicant's election with traverse of Group I in the reply filed on October 28, 2004 is acknowledged. The traversal is on the ground(s) that the burden to examine all the claims in a single application is less than that of Applicants to prosecute more than one application, and a search of group I will necessarily require a search of group II. This is not found persuasive because initially, a comparison of burden between examination of an invention and Applicants requirements for prosecution is not the basis of a restriction requirement, in particular because Applicants particular burden is not even set forth in the traversal. With respect to the search, there is no requirement to search all the necessary art associated with genetic engineering that would be associated with group II in the search of a hepatic precursor cell, therefore the search of Group I would not coextensive and include all the embodiments of the invention of group II.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-20 are pending. Claims 11-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on October 28, 2004. Claims 1-10, drawn to a liver precursor cell capable of differentiating into biliary cells, are currently under examination.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:
Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

Specifically, on the signature page of the declaration the address information for Andreas Ochs has been amended.

Specification

The disclosure is objected to because of the following informalities: the priority data presented in the first line of the specification appears to be incorrect, in particular the listing of 08/256,696 as a priority document.

Appropriate correction is required.

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application); the disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994). In this case, the listing of 08/256,696 and its contents do not support this requirement. Neither the inventors nor the specification support a claim for priority.

Additionally, it is noted that an application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a

prior application of a CPA assigned the same application number. In this case 08/256,696 does not appear to be related to the instant application.

If applicant desires priority under 35 U.S.C. 120 based upon a previously filed application, specific reference to the earlier filed application must be made in the instant application. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph unless it appears in an application data sheet. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. _____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or

120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Information Disclosure Statement

The information disclosure statement (IDS) submitted is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Objections

Claim 7 is objected to because of the following informalities: The use of the trademark Millicell has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claims 2-9 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

As written claim 2 sets forth capabilities of the claimed precursor cell which appear to be inherent properties of the claimed cell. Therefore, claims 2-9 do not further limit claim 1.

Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-10 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Specifically, the claims are directed to compositions comprising immature animal cells including liver, pancreas, gut, lung or bone marrow cells, all which can be present as composition in the context of a embryo, fetus and an adult human. As written in light of the teachings of the instant specification the claimed cells read on cells that are a human

embryo. A human being or human embryo is not-statutory subject matter. See 1077 O.G. 24, April 21, 1987.

Amending the claim to recite an "isolated" composition or a non-human composition of cells would address the basis of the rejection.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1, 2, 3, 4, 8-10 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 3-7 of prior U.S. Patent No. 5,789,246. This is a double patenting rejection.

The claims of the present application, which is dependent on claim 1, is exactly the same in wording and scope as claims indicated above of patent 5,789,246. For example, claims 1 and 2 recite all the limitations present in claim 1 of the patent.

Claims 1, 6, 7 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 2, 3 of 6,146,889. Claims 1 are duplicates of each other. Claims 6, 7, recite further limitations to claim 1 of the present application and are exact duplicates of claims 2 and 3.

Obvious Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 10-22 of U.S. Patent No. 6,146,889. Although the conflicting claims are not identical, they are not patentably distinct from each other because each recite a composition of hepatocyte precursor cells with certain capabilities in certain environments.

Claims 1-10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 3 of U.S. Patent No. 5,576,207. Although the

conflicting claims are not identical, they are not patentably distinct from each because the methods of '207 require the instantly claimed product with the claimed capabilities.

Claims 1-10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 3 of U.S. Patent No.5,789,246. Although the conflicting claims are not identical, they are not patentably distinct from each other. For example, claims 1 and 3 of U.S. Patent No. 5,789,246 recites a composition of cells derived ***in a*** serum free culture medium, extracellular matrix and liver stromal cells (emphasis added for correction made in application but not in the published patent). The culturing conditions which makes-up the composition recited in claim 1 comprises any extracellular matrix, and claim 3 states that specific components of the extracellular matrix can be added in any combination thereof. Collagen, fibronectin, laminin and proteoglycans are all compounds which are defined as components of the extracellular matrix. Therefore, claims 1 and 3 recite a composition which encompasses any specific extracellular matrix in any number of number of combinations. Claim 2 of the instant application recites a composition which clearly encompasses the composition of claims 1 and 3 of patent 5,789,246, because claim 2 simply restates that the extracellular matrix can be any combination of components. So in comparing the limitations of the claims, the vagueness and variation of the extracellular compounds recited in patent 5,789,246 encompasses any limitation recited in claim 5 of the instant application. While claims 1 and 3 do not specifically recite that the culture should include proteoglycans or that the extracellular matrix is derived from tissue extracts in the claims,, optimization of culturing conditions is generally

accepted as routine in the art. Further, one can compare other specific dependent claims; 10 to 7, 3 to 3, 8 to 6, for specific limitations that are duplicates of each other.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, claim 2 sets forth that the hepatocyte precursor cells "are capable of" a set of particular properties and review of the teachings of the specification teaches that these are observed properties of the claimed cell. However, there is no teaching that different populations exist wherein separate populations have one, some or all of the claimed properties. Therefore, as written claims 2-9 are confusing and unclear because what is being claimed appears to be an inherent property of the cell claimed in claim 1, and the metes and bounds of the claims set forth by these dependent claims are indefinite because it is unclear how they further limit claim 1 or what cells from claim 1 specifically have the claimed capablities.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Kuri-Harcuch *et al.* (US Patent 5,030,105-IDS reference).

Claim 1 as written broadly encompasses any composition of immature animal cells that contains a population of cells that are capable of differentiating into hepatocytes. Except for dependent claim 10, the dependent claims set forth the capabilities of the claimed precursor cell, however they do not appear to further limit the claimed precursor cell because the simply set forth inherent properties of the claimed cell. The claims as written broadly encompass a liver, since the liver would contain the composition of cells instantly claimed. Kuri-Harcuch *et al.* teach an isolated liver (see for example working Example 1). In addition, Kuri-Harcuch *et al.* provide guidance such as media and appropriate substrates for the *in vitro* culturing of populations of cells from a perfused liver for various purposes (see for example column 3, lines 45-50). Further, it is taught the methods will support the in vitro growth of various cells that can be isolated from the liver besides hepatocytes (see for example column 3, lines 3-33). In Example 1, a perfusion of the liver is done and the cells

Claims are rejected under 35 U.S.C. 102(b) as being anticipated by Tsai *et al.* (Biol. Abstr. 22434-IDS reference).

Claim 1 is drawn to a composition of cells capable of differentiating into hepatocytes, and sets forth that the composition includes liver, pancreas, gut, lung and bone marrow cells (see

claim 1). Dependent claims 2-9 set forth properties of which the cell is capable, the cell, and claim 10 states that the composition further comprises a growth factor. The claims as written broadly encompass a composition of liver, pancreas, gut, lung and bone marrow cells. Tsai *et al.* teach a population of isolated fetal liver and human adult bone marrow progenitor cells. Tsai *et al.* teach conditions for culturing the cells and indicate that ST-1 cells provide growth factors to the media when cultured as a composition *in vitro*.

Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. See *In re Ludtke* 441 F.2d 660, 169 USPQ 563 (CCPA 1971). Whether the rejection is based on "inherency" under 35 USC 102, or "prima facie obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. *In re Best, Bolton, and Shaw*, 195 USPQ 430, 433 (CCPA 1977) citing *In re Brown*, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972).

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (571) 272-0734.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach

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AU1632